

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

ARBUTUS BIOPHARMA CORPORATION  
and GENEVANT SCIENCES GMBH

*Plaintiffs,*

v.

MODERNA, INC. and MODERNATX,  
INC.,

*Defendants.*

**Redacted - Public Version**

C.A. No. 22-252-JDW

MODERNA, INC. and MODERNATX,  
INC.,

*Counterclaim-Plaintiffs,*

v.

ARBUTUS BIOPHARMA CORPORATION  
and GENEVANT SCIENCES GMBH,

*Counterclaim- Defendants.*

**JURY TRIAL DEMANDED**

**PLAINTIFFS' OPENING BRIEF IN SUPPORT OF**  
**MOTION TO EXCLUDE CERTAIN EXPERT TESTIMONY**  
**OF DRS. ANDERSON AND PRUD'HOMME**

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## **I. NATURE AND STAGE OF PROCEEDINGS AND SUMMARY OF ARGUMENT**

In connection with their motion for summary judgment, Plaintiffs move to exclude certain testimony from Moderna’s experts, Dr. Anderson and Dr. Prud’homme.

**First**, issue preclusion and statutory estoppel under 35 U.S.C. § 315(e)(2) foreclose Dr. Anderson’s obviousness opinions contradicting the final decisions of the PTO’s Patent Trial and Appeal Board (“PTAB”) and the Federal Circuit rejecting Moderna’s prior obviousness challenges to the Lipid Composition Patents. *Moderna Therapeutics, Inc. v. Protiva Biotherapeutics, Inc.*, 2019 Pat. App. LEXIS 13612, at \*1 (P.T.A.B. Sept. 11, 2019) (“’435 FWD”); *ModernaTx, Inc. v. Arbutus Biopharma Corp.*, 18 F.4th 1364 (Fed. Cir. 2021) (“’069 Decision”). Dr. Anderson raises the same obviousness arguments based on “routine optimization” of purported lipid ranges in the prior art rejected squarely by the PTAB and Federal Circuit. Those opinions should be excluded because they are estopped by the plain text of § 315(e)(2) and issue precluded.

**Second**, in opining that the asserted claims of the Lipid Composition Patents and the ’651 patent are invalid for lack of enablement, Dr. Prud’homme premises his opinions on erroneous legal standards that violate controlling law and should thus be excluded. Dr. Prud’homme misconstrues the claims to require various unrecited functional properties (such as potency and stability), brazenly ignores the well-established “any mode” rule of enablement, and improperly presents non-infringement arguments under the guise of enablement.

This motion is being filed pursuant to Chief Judge Goldberg’s Order, D.I. 485 ¶ 6, solely to identify expert evidence that the Court should not consider in resolving Plaintiffs’ motion for summary judgment on Moderna’s nonobviousness and non-enablement defenses. Plaintiffs will file additional *Daubert* challenges pursuant to the schedule set forth in D.I. 485.

## **II. LEGAL STANDARD**

The Federal Rules of Evidence—and in particular Rule 702—“assign to the trial judge the

task of ensuring that an expert’s testimony both rests on a reliable foundation and is relevant to the task at hand.” *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 597 (1993). The party offering the expert testimony has the burden of establishing its admissibility by a preponderance of the evidence. *See* Fed. R. Evid. 702. Per Rule 702, expert testimony must (a) “help the trier of fact to understand the evidence or to determine a fact in issue;” (b) be “based on sufficient facts or data;” (c) be “the product of reliable principles and methods;” and (d) “reflect[] a reliable application of the principles and methods to the facts of the case.”

Expert testimony must “relate to an[] issue in the case” and not unduly risk “confusion of the issues, or misleading the jury.” *Daubert*, 509 U.S. at 591, 595. “Proposed testimony must be supported by appropriate validation—*i.e.*, ‘good grounds,’” rather “than subjective belief or unsupported speculation.” *Id.* at 589–90. Critically, Rule 702 bars testimony based on “markedly incorrect law,” *Hebert v. Lisle Corp.*, 99 F.3d 1109, 1117 (Fed. Cir. 1996), or “an incorrect legal standard,” *Intuitive Surgical, Inc. v. Auris Health, Inc.*, 549 F. Supp. 3d 362, 370-71 (D. Del. 2021).

### **III. STATUTORY ESTOPPEL AND ISSUE PRECLUSION FORECLOSE DR. ANDERSON’S OBVIOUSNESS OPINIONS**

Moderna seeks to relitigate the outcome-determinative obviousness findings from its failed *inter partes* reviews (“IPRs”) through the opinions of its obviousness expert, Dr. Daniel Anderson. Both statutory estoppel and issue preclusion warrant exclusion of Dr. Anderson’s foreclosed opinions. Plaintiffs’ analysis of statutory estoppel and the four issue preclusion factors herein is substantially identical to the analysis of those issues set forth in Plaintiffs’ contemporaneously filed motion for summary judgment. It is raised here as well pursuant to Chief Judge Goldberg’s procedure, D.I. 485 ¶ 6, because Dr. Anderson’s violations of statutory estoppel and issue preclusion principles are also grounds for exclusion under Rule 702 and therefore should not be considered in determining summary judgment of nonobviousness.

**A. Dr. Anderson’s Obviousness Opinions on the ’435 Patent Are Estopped Under 35 U.S.C. § 315(e)(2)**

35 U.S.C. § 315(e)(2) provides: a “petitioner in an [IPR] . . . *that results in a final written decision* . . . *may not assert* . . . in a civil action . . . that the claim is invalid *on any ground that the petitioner raised or reasonably could have raised* during that [IPR].” Moderna’s IPR petition on U.S. Patent 9,364,435 “result[ed] in a final written decision.” ’435 FWD, 2019 Pat. App. LEXIS 13612, at \*1. Thus, Moderna “may not assert” in this “civil action” “invalid[ity] on any ground that [it] raised or reasonably could have raised” in the IPR. § 315(e)(2). The statute bars all of Dr. Anderson’s obviousness opinions against the ’435 patent. Ex 4 (Anderson) ¶¶ 919-1042; Ex 6 (Anderson Reply) ¶¶ 113-247, 259-80, 287-88, 290-95, 304-07.<sup>1</sup>

The statutorily estopped arguments “that the petitioner ‘reasonably could have raised’ in its petition” are “invalidity grounds a skilled searcher conducting a diligent search reasonably could have been expected to discover.” *Ironburg Inventions Ltd. v. Valve Corp.*, 64 F.4th 1274, 1298 (Fed. Cir. 2023). Every obviousness reference Dr. Anderson asserts against the ’435 patent here could have been raised in the IPR. Ex 1 (Moderna’s Disclosures of Prior Art and Invalidity Defenses) at 4-5 (obviousness combinations); Ex 4 (Anderson) ¶¶ 945 (asserting obviousness based on the ’554 publication, Jadhav ’218, ’189 publication; the Semple 1996 and Semple Article publications; and the “2:40 Formulation,” which Dr. Anderson draws from multiple publications, *see* Ex. 6 Anderson ¶ 515); 949 (asserting same references), 958 (asserting same references), 966 (asserting same references along with Meulien ’831 patent; Heyes 2005 publication). Moderna agrees, in no uncertain terms, that it is not “asserting that there are any prior art publications that could not have been found by a skilled searcher.” Ex 2 (Sept. 19, 2023 Letter) at 9; Ex 3 (Moderna’s Final Invalidity Contentions) at 66. Moderna does not dispute that it “reasonably

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<sup>1</sup> Exhibit citations refer to the exhibits to the July 25, 2025 Declaration of Matthew W. Lachman.

could have raised” its obviousness grounds in its ’435 patent IPR. *Trs. of Columbia Univ. v. Symantec Corp.*, 390 F. Supp. 3d 665, 676-677 (E.D. Va. 2019).

Moderna does not have any other basis to oppose application of statutory estoppel. “The controlling principle in this case is the basic and unexceptional rule that courts must give effect to the clear meaning of statutes as written.” *Star Athletica, L.L.C. v. Varsity Brands, Inc.*, 580 U.S. 405, 414 (2017). As explained in detail in Plaintiffs’ contemporaneously filed motion for summary judgment, Moderna’s argument that § 315(e)(2) contains an atextual exception where an appeal from a final written decision is dismissed for lack of standing lacks any support in the statute as written or precedent. Accordingly, Dr. Anderson’s opinions asserting obviousness of the ’435 patent should be excluded. *Trustid, Inc. v. Next Caller Inc.*, 2021 WL 3015280, at \*1, \*4 (D. Del. July 6, 2021) (“preventing Defendant from asserting prior art defenses . . . based on estoppel under § 315(e)(2)” during appeal); *SiOnyx, LLC v. Hamamatsu Photonics K.K.*, 330 F. Supp. 3d 574, 601 (D. Mass. 2018) (estopping party from reraising grounds it could not appeal).

**B. Dr. Anderson’s Obviousness Opinions on the Lipid Composition Patents are Issue Precluded**

In asserting obviousness of the ’435 patent and U.S. Patents 8,492,359 and 11,141,378 (with U.S. Patent 8,058,069, the “Lipid Composition Patents”), Dr. Anderson seeks to revisit the findings of the PTAB that the Federal Circuit affirmed in the non-dismissed ’069 patent appeal. *’069 Decision*, 18 F.4th at 1376-77. Moderna’s “inability to prove” obviousness “under the lower preponderance . . . standard at the PTAB” precludes it “from raising the argument under the higher clear and convincing evidence standard in district court” through Dr. Anderson’s testimony. *SynQor, Inc. v. Vicor Corp.*, 2022 WL 6217132, at \*17 (E.D. Tex. Sept. 26, 2022).

Agency decisions, like IPR decisions, may trigger issue preclusion. *Papst Licensing GmbH v. Samsung Elecs. Am.*, 924 F.3d 1243, 1250-51 (Fed. Cir. 2010); *B&B Hardware, Inc. v. Hargis*

*Industries, Inc.*, 575 U.S. 138, 148 (2015). Issue preclusion applies when (1) the same issue was previously adjudicated; (2) the issue was actually and finally decided; (3) the previous determination was necessary to the decision; and (4) the party being precluded was fully represented in the prior action. *Papst*, 924 F.3d at 1250-51; *Jean Alexander Cosmetics, Inc. v. L'Oreal USA, Inc.*, 458 F.3d 244, 249 (3d Cir. 2006). These elements are satisfied here, warranting exclusion of Dr. Anderson's obviousness opinions on the Lipid Composition Patents.

### **1. Moderna Seeks to Relitigate the Same Issues**

Although the '069 patent is no longer at issue for the upcoming trial, following the recent narrowing of claims and defenses ordered by Judge Goldberg, D.I. 475, the remaining Lipid Composition Patents share the same specification, and the obviousness analysis is materially the same for the asserted claims. Dr. Anderson advances obviousness opinions against these claims that the PTAB and Federal Circuit already rejected: that (1) it was "routine" to optimize the lipid components and amounts in LNPs based on the prior art, and (2) the prior art taught a range of phospholipid that overlaps with the claimed ranges.

**"Routine Optimization."** The Lipid Composition Patents' claims recite nucleic acid-lipid particles comprising four lipid components: (1) a cationic lipid, (2) a conjugated lipid, and a non-cationic lipid including (3) cholesterol and (4) a phospholipid. *E.g.*, '435 patent, claim 7; '069 *Decision*, 18 F.4th at 1369. As relevant here, the claims recite ranges of the four lipids' molar ratios. Since the prior art does not disclose particles with the claimed molar ratio ranges (Moderna does not assert anticipation), Moderna argued both before the PTAB and on appeal that it would have been routine for the person of ordinary skill in the art ("POSA") to optimize the lipid particle formulations in the prior art, which had different lipids and/or ratios, to arrive at the claimed ranges. '069 *Decision*, 18 F.4th at 1376 ("Moderna argues that . . . [prior art] presented a starting point that would have allowed a [POSA] to arrive at the claimed invention through routine

optimization.”). For example, because the prior art did not disclose a phospholipid range, Moderna argued that “the phospholipid range would have been obtainable through routine optimization using disclosed prior art formulations as starting points.” *Id.* at 1369. Moderna specifically urged that routine optimization would use the prior art “2:40 [conjugated:cationic] formulation” as a “starting point[],” and that the POSA would “increase the amount of cationic lipid,” among other changes “to each *individual* component.” *Id.* at 1376 (emphasis added). Moderna relied on the prior art ’189 publication, which taught the 2:40 formulation, the ’554 publication, and other references. *Id.* at 1368-69.

The PTAB and the Federal Circuit both rejected Moderna’s obviousness theory decisively, finding that Moderna’s routine optimization argument failed “to address the interdependence of the claimed lipid components” and their “unpredictable interactivity.” *Id.* at 1376-77. Yet Dr. Anderson revisits this exact issue here, as illustrated below (with emphases added):

PTAB and Federal Circuit Findings	Dr. Anderson’s Opinions in this Case
<p>“[O]ptimizing the four interdependent lipid components in the prior art nucleic acid-lipid particles <b>would not have been routine</b>” and concluding that there was “<b>unpredictable interactivity</b> between the various lipid components.” ’069 Decision, 18 F.4th at 1377.</p> <p>“We are not persuaded by Petitioner’s <b>routine optimization</b> argument at least as applied to the claimed phospholipid range.” <i>Moderna Therapeutics, Inc. v. Arbutus Biopharma Corp.</i>, 2020 WL 4237232, at *13 (P.T.A.B. July 23, 2020) (“’069 FWD”).</p> <p>[W]e <b>are not persuaded</b> that [Chen ’554] teaches an overlapping phospholipid range such that the claims are prima facie obvious or that the adjustment of the phospholipid amount to within the claimed range would have been a matter of <b>routine optimization</b>.” <i>Id.</i> at *17.</p>	<p>“In my opinion, it would only take <b>routine optimization</b> for the POSA to arrive at the claimed molar ratios . . . .” Ex 4 (Anderson) ¶ 967.</p> <p>The POSA would identify the phospholipid range “in doing <b>routine optimization</b> of lipid molar ratios.” <i>Id.</i> ¶ 823.</p> <p>“[U]sing <b>routine optimization</b>, a POSA would have arrived at the claimed mole percent of phospholipid and cholesterol.” <i>Id.</i> ¶ 619.</p> <p>“Using <b>routine optimization</b>, a POSA would have arrived at the claimed mole percent of phospholipid.” <i>Id.</i> ¶ 722.</p>

There is no difference between Moderna's arguments here (through Dr. Anderson's opinions) or the claims at issue that allows a second bite at the apple. Indeed, after Plaintiffs' expert, Dr. Niren Murthy, explained that Dr. Anderson had advanced opinions "considered and rejected by the PTAB and/or the [Federal Circuit]," Ex 5 (Murthy) ¶ 260, Dr. Anderson, in his 169-page Reply Report, does not dispute that fact or identify a single difference between his "Routine Experimentation" or "optimization" theory and the "routine optimization" theory the PTAB and Federal Circuit rejected. *E.g.*, Ex 6 (Anderson Reply) ¶¶ 151, 243; § VIII.D. Instead, Dr. Anderson noted that he "cite[s] prior art" not addressed in the prior decisions and that the asserted claims are not identical to the '069 patent. *Id.* ¶ 134. Neither creates a new issue.

**First**, Dr. Anderson citing prior art that was not before the PTAB or Federal Circuit is irrelevant to the issue preclusion analysis. As the Federal Circuit and this District have held repeatedly, a defendant's attempt to "buttress [its] case through different [prior art] evidence" does not create a new issue. *Dana v. E.S. Originals, Inc.*, 342 F.3d 1320, 1325 (Fed. Cir. 2003); *PureWick Corp. v. Sage Products, LLC*, 2023 WL 2734779, at \*5 (D. Del. Mar. 31, 2023); *see also Rudolph Techs., Inc. v. Camtek Ltd.*, 2016 WL 8668504, at \*5 (D. Minn. Aug. 8, 2016) ("[I]ssue preclusion applies even if the underlying theory or evidence proffered in the second action is different."); Restatement (Second) of Judgments § 27 cmt. c, illus. 4. Although these cases involved challenges to the same patent(s) in both proceedings, the reasoning applies here. *See Papst*, 924 F.3d at 1249-50 (applying issue preclusion where patents differed between actions); *Amgen, Inc. v. Genetics Inst., Inc.*, 98 F.3d 1328, 1332 (Fed. Cir. 1996) (same). The Court should thus reject a "granular view" of issue preclusion and "decline[] to parse . . . obviousness further" based on Moderna's particular prior art. *PureWick*, 2023 WL 2734779, at \*5.

Even were the particular references relevant, however, none of Moderna's prior art (Ex 1)

presents an obviousness issue materially different from what the PTAB and Federal Circuit already decided. Dr. Anderson cites “Jadhav ’218” but never asserts that it provides a substantively different teaching related to routine optimization, Ex 4 (Anderson) ¶¶ 824-825, 946-948, or that it somehow negates the prior finding that “the lipid components of the nucleic acid-lipid particle are interdependent” and “interact with each other unpredictably,” foreclosing routine optimization. *’069 Decision*, 18 F.4th at 1374. On the contrary, Dr. Anderson did not dispute Dr. Murthy’s opinion that the Jadhav ’218 disclosure “is substantially similar if not identical” to the ’554 publication the PTAB and Federal Circuit addressed. Ex 5 (Murthy), ¶ 300; Ex 6 (Anderson Reply) ¶¶ 35-36. Moderna cannot avert issue preclusion by citing a separate reference with “substantially identical teachings with respect to” the relevant issues. *Power Integrations, Inc. v. Fairchild Semiconductor Int’l, Inc.*, 763 F. Supp. 2d 671, 679-80 (D. Del. 2010).

Similarly, Dr. Anderson cites to purported teachings to use a lower amount of cholesterol to enhance “liposome recovery,” Ex 4 (Anderson) ¶ 1005 (citing Semple 1996). But again, Dr. Anderson does not assert that this prior art teaches the claimed lipid ranges. It instead merely provides a different permutation of Moderna’s already-litigated “general considerations to be taken into account with respect to each individual component” (in this case, the cholesterol component), which the Federal Circuit rejected as “fail[ing] to address the interdependence of the claimed lipid components and how adjustments would affect the nucleic acid-lipid particle as a whole,” especially in view of the components’ “unpredictable interactivity.” *’069 Decision*, 18 F.4th at 1376-77. In other words, every change to an *individual* lipid concentration necessitates changes to the *other components*, because they sum to 100%, and the Federal Circuit found that the consequences of those changes are unpredictable and not routinely optimized. *Id.* Ignoring this finding, Moderna’s approach again focuses myopically on individual lipid adjustments in isolation

and fails to account for the “unpredictable” effect of those adjustments on the particle as a whole. *Id.* Moderna’s argument thus fails for the same reasons as its prior rejected argument.

The same applies to Dr. Anderson’s opinion that a POSA would have increased “cationic lipid[] at the expense of phospholipid” to improve “encapsulation and transfection efficiency,” Ex 4 (Anderson) ¶ 996-97 (citing Sempel Article), as the Federal Circuit rejected Moderna’s argument “to increase the amount of cationic lipid to increase transfection efficiency” as a basis for routine optimization. *’069 Decision*, 18 F.4th at 1376. Dr. Anderson relies on the “2:40” formulation disclosed in the ’189 publication and elsewhere, Ex 4 (Anderson) ¶ 618, yet the PTAB and Federal Circuit considered Moderna’s same argument on this same formulation “as [a] starting point[] for optimization” and found that it did not support achieving the claimed ranges through routine optimization, *’069 Decision*, 18 F.4th at 1376; *’069 FWD*, 2020 WL 4237232, at \*15 (proposed “adjustments” to 2:40 formulation “hindsight driven” and not “routine optimization”).

**Second**, there is no difference between the claims of the Lipid Composition Patent at issue here and the ’069 patent’s claims that is relevant for issue preclusion purposes. Like the ’069 patent claims the PTAB and Federal Circuit upheld, all but two asserted claims recite ranges for the phospholipid component, in addition to requiring the same other three lipids. Though the numerical endpoints of certain of the lipid ranges differ between the asserted claims and the previously adjudicated claims, the distinctions are immaterial to Moderna’s obviousness theory. Neither the Federal Circuit nor the PTAB decision turned on the specific numerical endpoints but rather on the “unpredictable interactivity between the” four recited lipid components, *’069 Decision*, 18 F.4th at 1377—which are common to the ’069 patent and the asserted claims—and the absence of *any* prior art teaching of a phospholipid range (discussed further below), *id.* at 1374-75. And regardless, the “calculated” phospholipid range of “0-19.5 mol %” Moderna relied upon

(rejected by the PTAB and Federal Circuit) overlaps with the asserted claims just like the '069 patent claims. *Id.* at 1375. Thus, because “the differences between the unadjudicated patent claims and adjudicated patent claims do not materially alter the question of invalidity, [issue preclusion] applies.” *Ohio Willow Wood Co. v. Alps South, LLC*, 735 F.3d 1333, 1342 (Fed. Cir. 2013).

The only distinction Dr. Anderson notes between the '069 claims and those at issue here is that the '378 patent claims “are not limited to any amount of cationic lipid.” Ex 6 (Anderson Reply) ¶ 134. That distinction is immaterial as well: like the '069 patent, the '378 patent claims recite four lipid components and a particular range of phospholipid, and “the Board’s finding that optimizing the four interdependent lipid components in the prior art nucleic acid-lipid particles would not have been routine” therefore is dispositive. *'069 Decision*, 18 F.4th at 1376-77.

**“Overlapping Phospholipid Range.”** Along with rejecting Moderna’s routine optimization theory for lipid ratios, the PTAB and Federal Circuit found that the prior art '189 and '554 publications do not teach a phospholipid range, so no “overlapping [phospholipid] range is actually taught by the prior art,” and any “presumption of obviousness” did not apply. *'069 Decision*, 18 F.4th at 1373, 1375; *'069 FWD*, 2020 WL 4237232, at \*11-12 ('189 does not “explicitly disclose[] a phospholipid range”); *id.* at \*17 (same for '554); *see also '069 Decision*, 18 F.4th at 1374-75 (rejecting “premise that one could obtain a value for the amount of any one lipid component in the particle by adding up the amounts of the other three components and subtracting from 100%”). That preclusive finding forecloses Dr. Anderson’s contrary opinion that the prior art disclosed “Overlapping Ranges” giving rise to a “presumption of obviousness.” *E.g.*, Ex 4 (Anderson) ¶¶ 972-991. Moderna’s obviousness argument thus rests on the notion that a POSA could derive such a range through routine optimization. *See* Ex 4 (Anderson) ¶ 823 (“To the extent [the '189] does not . . . disclose this claim element, it would be obvious in view of the

knowledge of a POSA and/or obvious in combination with one or more of the prior art discussed below *in doing routine optimization of lipid molar ratios.*”). As discussed above, that is an improper effort to relitigate the PTAB’s and Federal Circuit’s findings.

\* \* \*

Because Moderna’s obviousness theories do not “materially alter the question of invalidity” decided by the PTAB and Federal Circuit, the issues are the “same” for purposes of issue preclusion. *Ohio Willow Wood*, 735 F.3d at 1342; *see PureWick*, 2023 WL 2734779, at \*5.

## **2. The Issues Were Actually and Finally Decided**

The dispositive findings discussed above were “determined by a valid and final judgment” of the PTAB, affirmed by the Federal Circuit. *Jean Alexander*, 458 F.3d at 249. Plaintiffs and Moderna “vigorously litigated” obviousness in the IPR and the ensuing appeal. *Id.* at 254.

## **3. The Previous Determinations Were Necessary to the PTAB’s and Federal Circuit’s Decisions**

In applying the “essential to the judgment” element, governing Third Circuit law holds “that independently sufficient alternative findings should be given preclusive effect.” *Jean Alexander*, 458 F.3d at 255. The PTAB and Federal Circuit’s nonobviousness conclusions are supported by the independent findings that (1) the POSA would not derive the claimed lipid ranges through routine optimization, *’069 Decision*, 18 F.4th at 1376-77; *’069 FWD*, 2020 WL 4237232, at \*13; and (2) the prior art did not teach a phospholipid range, *’069 Decision*, 18 F.4th at 1374-75; *’069 FWD*, 2020 WL 4237232, at \*12. And these findings were essential to the decisions, as the prior art’s failure to teach the phospholipid range or support routine optimization to arrive at the claimed lipid ranges explicitly was held sufficient to foreclose obviousness. *’069 Decision*, 18 F.4th at 1369; *’069 FWD*, 2020 WL 4237232, at \*11.

## **4. Moderna Was Adequately Represented in the Previous Action**

Moderna was represented by sophisticated counsel in the prior proceedings, *Jean Alexander*, 458 F.3d at 249; *'069 Decision*, 18 F.4th at 1367 (WilmerHale); *'069 FWD*, 2020 WL 4237232 (Irell & Manella), and had a full opportunity to litigate obviousness before the PTAB and Federal Circuit. *PureWick*, 2023 WL 2734779, at \*10. This element is plainly satisfied.

**C. Exclusion of Dr. Anderson's Precluded Opinions Is Proper**

Statutory estoppel forecloses Dr. Anderson's obviousness opinions on the '435 patent, and issue preclusion forecloses his obviousness opinions on the Lipid Composition Patents which contradict the PTAB and Federal Circuit's nonobviousness judgment and their determinations that (1) "routine optimization" would not yield the claimed ranges due to "unpredictable interactivity" of the four lipid components, *'069 Decision*, 18 F.4th at 1376-77, and (2) the prior art does not disclose a phospholipid range, *id.* at 1374-75. Exclusion under Rule 702 is proper to prevent Moderna from adducing evidence in support of an obviousness theory Moderna is precluded from relitigating. *PureWick*, 2023 WL 2734779, at \*5; *Centripetal Networks, LLC v. Palo Alto Networks, Inc.*, 2024 WL 219124, at \*7 (E.D. Va. Jan. 9, 2024). The Court should thus exclude Dr. Anderson's obviousness opinions relating to the Lipid Composition Patents in their entirety. Ex. 4 (Anderson) §§ XII.C-XII.E, XIII; Ex. 6 (Anderson Reply) §§ VIII-IX.

**IV. DR. PRUD'HOMME'S NON-ENABLEMENT OPINIONS RELY ON ERRONEOUS LEGAL STANDARDS AND SHOULD BE EXCLUDED**

Dr. Prud'homme premises his non-enablement opinions on erroneous legal standards that violate black-letter Federal Circuit law and should therefore be excluded. The incongruence of his opinions with the proper legal standards renders his opinions irrelevant and unhelpful to the trier of fact in contravention of Rule 702.

The Federal Circuit "encourage[s] exercise of the trial court's gatekeeper authority when parties proffer, through purported experts, not only unproven science . . . but markedly incorrect

law.” *Hebert*, 99 F.3d at 1117; *Intuitive Surgical*, 549 F. Supp. 3d at 370–71 (excluding testimony “to the extent it relies on an incorrect legal standard”); *Baxalta Inc. v. Bayer Healthcare LLC*, 513 F. Supp. 3d 426, 447 (D. Del. 2021) (“Paragraph 10 recites an erroneous legal standard and I must exclude any testimony based on it.”); *GlaxoSmithKline LLC v. Glenmark Pharms. Inc.*, 2017 WL 8948975, at \*7 n.6 (D. Del. 2017), *report and recommendation adopted*, 2017 WL 2536468 (D. Del. 2017) (excluding portions of expert reports that were “predicated on a faulty application of the law[,]”); *In re Novatel Wireless Sec. Litig.*, 846 F. Supp. 2d 1104, 1108 (S.D. Cal. 2012) (“If erroneous legal conclusions form the basis of [the expert’s] rebuttal opinions, the Court fails to see . . . what else [the expert] would provide testimony on. . . . The Court finds the Defendants contention that this is a question of weight, not admissibility, unpersuasive.”).

Applying this directive, Chief Judge Connolly has held that “[t]estimony that is contrary to the law is not admissible under Rule 702.” *Koninklijke Philips N.V. v. Telit IoT Sols., Inc.*, 2023 WL 8600662, at \*1 (D. Del. Dec. 12, 2023); *see also Graco Inc. v. Carlisle Constr. Materials, LLC*, 2024 WL 5333341, at \*1 (D. Del. Nov. 21, 2024); *Cave v. Saxon Mortg. Servs., Inc.*, 2015 WL 6153754, at \*9 (E.D. Pa. Oct. 20, 2015) (portions of expert opinion that were “contrary to our prior rulings . . . are per se unreliable and inadmissible under *Daubert*”). Dr. Prud’homme’s enablement opinions fall squarely within this precedent and should be excluded.

**A. Dr. Prud’homme’s Enablement Opinions Improperly Import Unclaimed Functional Limitations and Should be Excluded**

**1. Lipid Composition Patents**

Dr. Prud’homme’s argument that the full scope of each claim of the Lipid Composition Patents is not enabled is premised on one skilled in the art being unable to achieve properties that the claims never recite, such as potency and stability. This flouts controlling law.

“Section 112 requires enablement of ‘only the claimed invention,’ not matter outside the

claims.” *McRO, Inc. v. Bandai Namco Games Am. Inc.*, 959 F.3d 1091, 1100 (Fed. Cir. 2020). Enablement thus turns on the experimentation required to make the particles “as claimed.” *Raytheon Co. v. Roper Corp.*, 724 F.2d 951, 956 (Fed. Cir. 1983); *Takeda Pharm. Co. v. Zydus Pharms. USA, Inc.*, 743 F.3d 1359, 1370 (Fed. Cir. 2014) (“In light of our conclusion that the [] patent does not require deagglomeration . . . we conclude that it is not invalid for lack of enablement based on a failure to explain when and how to do so.”). Simply put, unclaimed functional properties are irrelevant to the enablement analysis. *See United Therapeutics Corp. v. Liquidia Techs., Inc.*, 74 F.4th 1360, 1370 (Fed. Cir. 2023) (holding that “all that the claims require” is a therapeutically effective dose, as written in the claim language, and that evidence of lack of safety “may be an issue for the FDA” but is irrelevant for enablement); *Alcon Rsch. Ltd. v. Barr Lab’ys, Inc.*, 745 F.3d 1180, 1188–89 (Fed. Cir. 2014) (for a claim reciting “a chemically-stabilizing” amount of a compound, the “district court erred in its enablement analysis,” because the claims “do not require a particular level of stability,” and thus “[a]djusting variables may be relevant to *optimizing* the stability of a given [] composition, but [defendant] proffered no evidence that any experimentation, let alone undue experimentation, with those variables would be necessary in order to *practice* the claimed invention”).

The asserted Lipid Composition claims recite “a nucleic acid-lipid particle comprising” nucleic acid and four lipids with indicated ratios (and, for one claim, a method of administering those particles). *E.g.*, ‘435 patent, claim 7. The claims do not recite any functional limitations that the particles must possess, such as stability, efficacy, or safety. During its IPR challenge of the ‘435 patent, Moderna urged the PTAB to “reject” any “attempt to interject additional limitations into the claims,” including limitations related to stability. ‘435 *FWD*, 2019 Pat. App. LEXIS 13612, at \*10-13; Petitioner’s Reply ‘435 Patent at 3-5. The PTAB held that the term

“nucleic acid-lipid particle” means “a particle that comprises a nucleic acid and lipids, in which the nucleic acid may be encapsulated in the lipid portion of the particle,” without further requirements, ’435 *FWD*, 2019 Pat. App. LEXIS 13612 at \*13, and Moderna explicitly “agree[d]” with this construction, Ex 29 (Moderna ’435 IPR Reply) at 3. In this litigation, Moderna did not propose a different definition for that term, nor did Moderna propose that any other term be construed to require additional properties.

In asserting non-enablement, however, Dr. Prud’homme interpreted the claims to require properties such as stability, potency, and tolerability. *E.g.*, Ex 7 (Prud’homme) ¶¶ 251 (“[T]he ‘present invention’ is not just directed to particles that can be created, but rather, particles that ‘provide advantages’ like **stability**, increased **activity** of the nucleic acid, improved **tolerability**, increased **therapeutic index**, etc.” (emphasis added)), 252 (relying on arguments Plaintiffs made, in describing the state of the art during the IPR proceedings, about the “unpredictability” of “the properties of nucleic acid-lipid particles,” which “depend on the particle as a whole, rather than on any one component” and could affect whether the particles are “**suitable for systemic use**” (emphasis added)). Dr. Prud’homme incorporated these opinions throughout his enablement analyses. Ex 7 (Prud’homme) ¶¶ 275, 287, 296, 322, 327.

Dr. Prud’homme sought to justify his claim redrafting by citing to the advantages described in the specification. *E.g.*, Ex 7 (Prud’homme) ¶ 291 (The “specification of the Molar Ratio Patents suggests that there is a level of stability that should be achieved by the claimed particles.”). Even were it proper for Dr. Prud’homme to construe a claim term contrary to Moderna’s interpretation before this Court and the Federal Circuit (it is not), his construction commits “one of the cardinal sins of patent law—reading a limitation from the written description into the claims.” *Phillips v. AWH Corp.*, 415 F.3d 1303, 1320 (Fed. Cir. 2005) (en banc); *i4i Ltd. v. Microsoft Corp.*, 598 F.3d

831, 843 (Fed. Cir. 2010) (“not every benefit flowing from an invention is a claim limitation”); *Golight, Inc. v. Wal-Mart Stores, Inc.*, 355 F.3d 1327, 1331 (Fed. Cir. 2004) (claims not required to include all “advantages or features described as significant or important”). Dr. Prud’homme also tries to justify importing unrecited claim features by citing Plaintiffs’ IPR statements about the unpredictability of unclaimed properties of nucleic acid-lipid particles and how this would have impacted a POSA’s motivation to combine prior art references. Ex 7 (Prud’homme) ¶ 252. Unclaimed features, although permissibly relevant to the motivation inquiry’s “reason to attempt” analysis, *see Chemours Co. FC, LLC v. Daikin Indus., Ltd.*, 4 F.4th 1370, 1377 (Fed. Cir. 2021), are irrelevant to the enablement inquiry, which turns on the experimentation required to make the particles “as claimed,” *Raytheon*, 724 F.2d at 956.

Dr. Prud’homme’s misinterpretation of the claims was significant. He repeatedly relied on unclaimed elements in opining that undue experimentation was required to practice the claims. *See, e.g.*, Ex 7 (Prud’homme) ¶¶ 265 (“[T]o determine whether a given formulation can achieve this higher level of **potency**, a POSA would be required to undergo **undue experimentation**.”), 241 n.11 (“[O]ne of the most important variables in forming **stable** LNPs and encapsulation efficiency of oligonucleotides is the solvent concentration . . . . The Molar Ratio Patents provide a POSA no guidance as to how to adjust the [ethanol] versus water concentration . . . . POSA would be required to perform **innumerable experiments** to choose a composition . . . and, for each trial composition, vary the pH and [ethanol] concentrations.”), 289 (citing experiments aimed at improving encapsulation efficiency as example of “**the undue level of experimentation**” required to practice the claims), 297 (in the context of the “nucleic acid-lipid particle,” opining that “the specification . . . suggests that the claimed particles possess certain **desirable properties**” like “**stability**” and “it would require a POSA to undergo **undue experimentation** . . . to determine

which specific formulations, if any, would fall within the claims”), 330-331 (“[O]ptimiz[ing] the composition for the *route of administration*” would require “*undue experimentation*.”) (all emphases added). These opinions make clear that Dr. Prud’homme based his enablement opinions on features and properties, such as potency, that the claims of the Lipid Composition Patents do not recite.

Plaintiffs’ expert Dr. Niren Murthy pointed out the impropriety of Dr. Prud’homme’s claim interpretations in his responsive expert report. *E.g.*, Ex 5 (Murthy) ¶¶ 1242 (“it appears to me that Dr. Prud’homme’s enablement opinions with respect to the Lipid Composition Patents are incorrectly premised on whether achieving unclaimed advantages would necessitate undue experimentation, not whether the inventions as actually claimed are enabled”), 1251, 1254, 1260, 1282, 1329, 1342.

In his Reply, Dr. Prud’homme did not dispute Dr. Murthy’s characterization of his opinions, or that he indeed based his enablement analysis on an improper claim interpretation. To the extent Dr. Prud’homme addressed the criticism at all, he justified his claim interpretation by citing Plaintiffs’ nonobviousness arguments regarding unexpected properties. *E.g.*, Ex 9 (Prud’homme Reply) ¶¶ 163, 193, 212. But reliance on unexpected properties to rebut obviousness does not transform those properties into claim limitations, for purposes of enablement or otherwise. *See, e.g., In re Merch.*, 575 F.2d 865, 869 (C.C.P.A. 1978) (“We are aware of no law requiring that unexpected results relied upon for patentability be recited in the claims.”); *Invista N. Am. S.A.R.L. v. M & G USA Corp.*, 35 F. Supp. 3d 583, 599 n.12 (D. Del. 2014) (criticizing expert who “conflated the ‘unexpected results,’ . . . an indicia of nonobviousness, and ‘undue experimentation’ as it applies to enablement, which is based on the invention as claimed”).

At his deposition, Dr. Prud’homme doubled down, confirming that—in assessing whether

the POSA could have practiced the claims without undue experimentation—he based his opinion on unclaimed properties, such as efficacy and stability. When asked whether it would require “undue experimentation” to practice Lipid Composition Patent claims, Dr. Prud’homme’s sole response was that Plaintiffs’ scientists “still had to do more and more experiments to get the desired results” such as “[t]herapeutic [*sic*], effectiveness, stability over time under freeze/thaw or some conditions.” Ex 10 (Prud’homme Tr.) 290:11-291:8; *id.* at 287:22-291:8 (Q. “Let me be clear. When I say ‘unsuccessful,’ I mean unsuccessful in practicing claim 1. Are you aware of anyone who’s ever tried to practice claim 1, make a particle within the scope of . . . claim 1 who has not succeeded in making a particle [of] claim 1?” A. “That’s my comment, that making a particle of claim 1 implies having a goal . . . [of] that particle having some properties that are useful, because patents require things that are useful, rather than just only the composition in claim 1.”). The functional properties Dr. Prud’homme cites *are* enabled, but regardless, Dr. Prud’homme’s opinions are irrelevant, as they are plainly directed to “matter outside of the claims,” contrary to Federal Circuit law. *McRO*, 959 F.3d at 1100; *Raytheon*, 724 F.2d at 956; *Takeda Pharm.*, 743 F.3d at 1370; *United Therapeutics Corp.*, 74 F.4th at 1370; *Alcon*, 745 F.3d at 1188-89.

Because Dr. Prud’homme’s non-enablement opinions rest on “markedly incorrect law,” they should be excluded. *Hebert*, 99 F.3d at 1117; *Intuitive Surgical*, 549 F. Supp. 3d at 370-71; *Baxalta*, 513 F. Supp. 3d at 447; *GlaxoSmithKline*, 2017 WL 2536468 at \*7 n.6; *Koninklijke Philips*, 2023 WL 8600662 at \*1. The Federal Circuit affirms the exclusion of expert testimony that relies on an incorrect legal standard or claim construction. *Treehouse Avatar LLC v. Valve Corp.*, 54 F.4th 709, 715 (Fed. Cir. 2022) (collecting cases); *Dominion Resources Inc. v. Alstom Grid, Inc.*, 2016 WL 7365185 at \*3 (E.D. Pa. May 16, 2016) (“To the extent [expert’s] opinion is directed at inadequate description or enablement of the accused *system*, rather than the more

limited claimed invention . . . we find such opinion and testimony unfit and inadmissible under Rule 702 . . .”). The Federal Circuit specifically has affirmed the exclusion of “expert testimony regarding enablement” as “irrelevant because it was based on an impermissible claim construction” and because “the evidence could prejudice and confuse the jury.” *Liquid Dynamics Corp. v. Vaughan Co.*, 449 F.3d 1209, 1224 n.2 (Fed. Cir. 2006); *see also Inline Connection Corp. v. AOL Time Warner Inc.*, 2007 WL 275928 at \*4-5 (D. Del. Jan. 29, 2007) (“[D]efendants ignore the rule that the specification ‘need not enable anything broader than the scope of the claims’” and as such, “[b]ecause [the expert] did not conduct a proper enablement analysis, his opinion is not reliable and is not admissible on enablement.” (citing *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 746 (3d Cir. 1994))). The following paragraphs of Dr. Prud’homme’s report explicitly refer to his improper construction and should be excluded: Ex 7 (Prud’homme) ¶¶ 241 n.11, 248 n.12, 250-253, 265, 275, 287-289, 291, 296-299, 315, 322, 323 n.16, 324, 327-331; Ex 9 (Prud’homme Reply) ¶¶ 162-163, 165, 173, 175-176, 179, 182, 185, 193, 203-204, 210, 212, 218.<sup>2</sup>

## 2. The ’651 Patent

Dr. Prud’homme likewise contends that the full scope of the asserted claims of the ’651 patent are not enabled based on his incorrect interpretation of the claims as requiring unclaimed properties, such as potency and stability. The claims are directed to lipid vesicle formulations with particular percentages of fully encapsulated mRNA; they do not recite or require the properties relied on by Dr. Prud’homme. His opinions are thus legally improper and should be excluded.

Dr. Prud’homme’s enablement analysis assumed, improperly, that the ’651 patent claims require various properties they do not recite, including at least efficacy, toxicity, and stability. *E.g.*, Ex 7 (Prud’homme) ¶¶ 151 n.5 (“The laundry list of ionizable lipids [from the specification]

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<sup>2</sup> This list includes all paragraphs containing the improper opinions, including those relating to arguments Moderna dropped in the claim narrowing process (which are separately foreclosed).

does not provide guidance for a POSA on which lipids to choose, and how *transfection efficiency*, *toxicity*, *LNP stability*, and *other effects* would depend on the lipid chosen. For this additional reason, all of the Asserted Claims are *not enabled*.”), 164 (claims not enabled because “the [ethanol] versus water concentration (as well as timing) will affect both *size and stability* of resulting LNPs” and because the specification provides “little to no information to a POSA relating to any of these steps or parameters”) (all emphases added)). Dr. Prud’homme incorporated these legally improper opinions throughout his non-enablement analysis. *Id.* ¶¶ 179, 199, 222.

As he did with the Lipid Composition Patents, Dr. Murthy points out Dr. Prud’homme’s misinterpretation of the ’651 patent claims. Ex 5 (Murthy) ¶¶ 638 (“I disagree that any of the properties that Dr. Prud’homme lists are relevant to the enablement inquiry. . . . Dr. Prud’homme’s assertion to the contrary suggests to me that he is misconstruing the claims, which appears to be the basis for his nonenablement opinions.”), 659 (“The asserted claims of the ’651 patent do not include particular size or stability requirements.”). Again, Dr. Prud’homme does not address or dispute that he interpreted the claims to include unrecited properties. *See, e.g.*, Ex 9 (Prud’homme Reply) ¶ 83 (ignoring Dr. Murthy’s criticism regarding no size or stability requirement). Though those unclaimed properties are in fact enabled, Dr. Prud’homme’s reliance on “matter outside of the claims” for his enablement opinion is in direct contravention of black-letter law. *Supra* Section IV.A.1. The following paragraphs of Dr. Prud’homme’s report explicitly refer to his improper construction and should be excluded: Ex 7 (Prud’homme) ¶¶ 151 n.5, 160, 164-165, 167, 179, 199, 222; Ex 9 (Prud’homme Reply) ¶¶ 70, 100, 115, 134.

**B. Dr. Prud’homme’s Opinions Improperly Assume that all Modes of Making the Invention Must be Enabled and Should be Excluded**

It is well established precedent “that the enablement requirement is met if the description enables any mode of making and using the invention.” *Johns Hopkins University v. CellPro, Inc.*,

152 F.3d 1342, 1361 (Fed. Cir. 1998) (affirming summary judgment of enablement). Where, as here, claims are directed to a composition rather than a method of making a composition, evidence of non-enablement of alternative modes of making and using the claimed invention is “legally irrelevant.” *Id.*; *Invitrogen Corp. v. Clontech Lab’ys, Inc.*, 429 F.3d 1052, 1071 (Fed. Cir. 2005) (affirming summary judgment of enablement because patent teaching one mode to practice the invention “is sufficient” where “the claims are not limited by the method of achieving the [invention]” explaining that “[e]nablement does not require the inventor to foresee every means of implementing an invention”). The law also is clear that the “dispositive question of enablement does not turn on whether the accused product is enabled.” *Pfizer Inc. v. Teva Pharms. U.S.A., Inc.*, 882 F. Supp. 2d 643, 682 (D. Del. 2012), *aff’d sub nom. Pfizer Inc. v. Teva Pharms. USA, Inc.*, 555 F. App’x 961 (Fed. Cir. 2014); *Inline Connection Corp. v. EarthLink, Inc.*, 684 F. Supp. 2d 496, 526 (D. Del. 2010) (“[Defendant’s] assertion that the patents must enable a system that can transmit up to 16,000 feet because that is the distance over which the accused system operates is flatly contrary to a proper enablement analysis.”).

Dr. Prud’homme violates this legal standard. He opines that the asserted claims are invalid because the ’651 patent does not enable alternative modes of making the claimed formulations, separate and apart from the methods disclosed in the specification. For example, Dr. Prud’homme opines that the patent fails to enable the claimed full encapsulation levels using *prior art* methods. *See, e.g.*, Ex 7 (Prud’homme) ¶ 182 (“[T]he specification actually explicitly acknowledges . . . that other methods would not achieve the claimed level of encapsulation,” citing patent’s statement that prior art methods cannot achieve the claimed invention). Dr. Prud’homme further opines that “[l]ater work by others also demonstrated that the use of *different methods* of making the vesicles can and does yield a different level of encapsulation,” citing an article published long after the

'651 patent regarding a distinct formulation method. Ex 7 (Prud'homme) ¶ 184. Dr. Prud'homme also opines that the '651 patent does not enable the encapsulation method Moderna uses to produce the *Accused Product*. Ex 7 (Prud'homme) ¶¶ 188-189. Dr. Prud'homme opines that these alleged failures to enable alternative modes proves non-enablement. *E.g.*, Ex 7 (Prud'homme) ¶¶ 185, 188-189 (“[T]he claims are not enabled for these additional reasons.”). Even assuming these arguments to be true for present purposes, they are precisely the types of critiques that the Federal Circuit has deemed “legally” irrelevant, because what matters is whether “the description enables *any* mode of making and using the invention.” *Johns Hopkins*, 152 F.3d at 1361. Dr. Prud'homme, in practice, is reading into the claims unclaimed language directed to all modes of making and using the claimed invention.

Plaintiffs' expert, Dr. Murthy, opined that evidence of non-enablement of alternative methods is irrelevant to enablement. *E.g.*, Ex 5 (Murthy) ¶¶ 664 (“I disagree that Dr. Heyes's declaration is relevant to the enablement inquiry. I note, for example, that the references being discussed used different formulation methods than those taught in the '651 patent and were directed towards different compositions.”), 676 (“As stated earlier, my understanding is that the enablement requirement is met if the description enables *any* mode of making and using the invention.”), 692 (“[N]either enablement nor written description would require an example in the patent using [the post-hoc loading] method.”), 693. Dr. Prud'homme did not modify his reliance on these opinions in reply. Ex 9 (Prud'homme Reply) ¶ 85.

As described above, the Federal Circuit has affirmed the exclusion of expert testimony that relies on an incorrect legal standard, including an erroneous reading in of unclaimed features. *Supra* Section IV.A; *EarthLink*, 684 F. Supp. 2d at 526-27 (D. Del. 2010) (“[Defendant's] accused product based enablement argument was previously rejected by the court in its preclusion of

Waring’s enablement testimony recited in his expert report.”). The following paragraphs explicitly refer to the improper alternative modes analysis and should be excluded: Ex 7 (Prud’homme) ¶¶ 182, 184-185, 188-189; Ex 9 (Prud’homme Reply) ¶¶ 73, 76, 100.

**C. Dr. Prud’homme’s Opinion Erroneously Importing a Measurement Requirement into the Enablement Standard Should be Excluded**

Enablement is satisfied if “one skilled in the art, having read the specification, could *practice* the invention without ‘undue experimentation.’” *Cephalon*, 707 F.3d at 1336 (emphasis added). Enablement does not depend on whether one skilled in the art could *measure* infringement or otherwise analyze the invention. *Therasense, Inc. v. Becton, Dickinson & Co.*, 560 F. Supp. 2d 835, 879 (N.D. Cal. 2008) (“[T]he test for enablement is . . . not whether one of ordinary skill of the art could easily assess whether” the device infringes.) *see also Eli Lilly & Co. v. Actavis Elizabeth LLC*, 435 F. Appx. 917, 925 (Fed. Cir. 2011) (“§ 112 requires nothing more than objective enablement”). Dr. Prud’homme’s opinions for both patent families violate this law.

**1. Lipid Composition Patents**

Dr. Prud’homme opines that the Lipid Composition Patent claims are not enabled because “a POSA would be required to undergo undue experimentation to determine whether a certain composition falls within the claims.” Ex 7 (Prud’homme) ¶ 256. Even if taken as true, enablement requires practicing, not measuring, the claimed invention. *Therasense*, 560 F. Supp. 2d at 879; *Eli Lilly*, 435 F. Appx. at 925. Dr. Murthy noted this legal error, Ex 5 (Murthy) ¶¶ 1247-1249, and Dr. Prud’homme again ignored these criticisms in his reply and did not correct or modify his opinion, Ex 9 (Prud’homme Reply) ¶¶ 162-166.

Dr. Prud’homme’s reliance on an erroneous enablement standard requires exclusion under Rule 702. *Supra* Section IV.A; *Inline Connection*, 2007 WL 275928 at \*5. The following paragraphs explicitly refer to the improper measurement analysis and should be excluded: Ex 7

(Prud'homme) ¶¶ 256-264, 275, 287, 296, 315, 322, 327; Ex 11 (Prud'homme Reply) ¶¶ 148, 162, 173, 182, 192, 203, 210.

## 2. '651 Patent

Dr. Prud'homme extends his improper measurement requirement to the '651 patent. The Court adopted Moderna's proposal, construing the claims as follows: "wherein at least 70% /at least 80% / about 90% of the mRNA in the formulation is fully, as distinct from partially, contained inside the lipid vesicles." D.I. 266 at 37. The Court clarified that a POSA "would only count those strands that are fully contained inside the vesicle" as fully encapsulated, and thus within the scope of the claims. *Id.* at 36. Dr. Prud'homme asserts non-enablement, claiming it would require undue experimentation to measure partially encapsulated mRNA. Ex 7 (Prud'homme) ¶¶ 170-171.

Even taking this assertion as true for present purposes, Dr. Prud'homme's opinions warrant exclusion as he again conflates Moderna's non-infringement arguments with non-enablement, which defies precedent as described above. *Therasense*, 560 F. Supp. 2d at 879; *Eli Lilly*, 435 F. Appx. at 925. Dr. Murthy opines that "the POSA reading the specification and using their knowledge in the field would have known that full encapsulation can be measured using a dye-exclusion assay, with orthogonal assays that could be used to confirm the state of the system." Ex 5 (Murthy) ¶ 574. Dr. Prud'homme does not opine that running a dye exclusion or orthogonal assay would require undue experimentation or dispute that running a dye exclusion assay is anything other than "relatively quick, cheap, and easy." Ex 5 (Murthy) ¶ 674; Ex 9 (Prud'homme Reply) ¶¶ 62, 86, 92. His opinion is not about the routineness of the assays but instead about whether dye exclusion assays can distinguish the percentage of fully encapsulated mRNA (*i.e.*, whether dye exclusion assays can be used to assess infringement). Ex 9 (Prud'homme Reply) ¶ 46 n.3. This is a plain attempt to dress up a non-infringement argument as non-enablement.

Dr. Prud'homme's reliance on an erroneous enablement standard requires exclusion per

Rule 702. *Supra* Section IV.C.1; *Inline Connection*, 2007 WL 275928 at \*5. The following paragraphs containing the improper measurement analysis merit exclusion: Ex 7 (Prud'homme) ¶¶ 126, 166, 170-171, 179, 199, 222; Ex 11 (Prud'homme Reply) ¶ 31, 70, 100, 115, 134.

## V. CONCLUSION

The Court should exclude Dr. Anderson's opinions regarding obviousness of the Lipid Composition Patents and Dr. Prud'homme's opinions regarding enablement.

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**CERTIFICATE OF SERVICE**

I hereby certify that on July 25, 2025, this document was served on the persons listed below in the manner indicated:

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